UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

MARK WILLIAMS and CAROL WILLIAMS, Plaintiffs, vs. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 5:14-cv-00460

DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL THE PRODUCTION OF SALES REPRESENTATIVES' PARTIAL CUSTODIAL FILES

Plaintiffs' motion acknowledges that their claims arise from the core theory that Lilly did not adequately warn of the risk of discontinuation symptoms when stopping Cymbalta treatment. Although North Carolina law provides that the relevant focal point in this failure-to-warn suit is the decisionmaking of the prescribing healthcare professional, Plaintiffs move to compel discovery from the files of sales representatives who never interacted with Mr. Williams' prescribing doctor. Indeed, Plaintiffs seek the "custodial files" of six sales representatives who visited two physicians who did not treat Mr. Williams until more than five months after he stopped taking Cymbalta. Plaintiffs simultaneously seek to abandon a date limitation protocol for sales representative discovery that Plaintiffs' counsel proposed in this and other Cymbalta litigation; that Lilly agreed to in good faith; and on which sales representative document discovery has proceeded in other litigation.

Ultimately, however, Plaintiffs fail to establish any connection between the sales representative discovery they seek through this motion and the claims in this case. Indeed, Plaintiffs' apparent willingness to abandon these requests entirely in favor of an admission of causation by Lilly (Pl. Mem. at 4) constitutes an acknowledgement that none of the discovery at issue here is critical to their claims. But the Federal Rules do not permit a party to use the *in terrorem* effect of threatened discovery as a tool to extract unrelated case concessions. Rather, the Rules envision that discovery will provide a vehicle for

gathering facts relevant to the claims at issue and proportional to what is at stake in the litigation. The discovery sought here does not meet that standard, and the Court should deny Plaintiffs' motion.

BACKGROUND

I. Plaintiffs' Claims

Cymbalta is an FDA-approved prescription medication used to treat various pain and psychiatric disorders. Plaintiffs' case is one of many pending across the country, each of which claims that Lilly failed to warn adequately of the risk of potential symptoms upon discontinuation of Cymbalta. Of the cases litigated to a merits determination to date, Lilly has won summary judgment in two suits (including on the adequacy of the Cymbalta discontinuation warning) and prevailed in three trials involving four plaintiffs, including securing a jury finding that the Cymbalta warning was adequate.[1]

Plaintiff Mark Williams was prescribed Cymbalta in February 2012 for treatment of hip pain. *See* First Amended Complaint, ECF No. 31, at ¶ 37. He never actually filled a prescription, having taken only samples of Cymbalta provided by his physician, Dr. Lesley Browder. *See* Declaration of Brett Reynolds Ex. 1 at 245, 253-57, 285. Mr. Williams took Cymbalta for a total of 17 or 18 days before discontinuing the medication. *See id.* Mr. Williams alleges that upon discontinuing Cymbalta, he experienced a variety of symptoms. First Amended Complaint ¶ 39. In August 2012, five months after discontinuing Cymbalta, Mr. Williams sought treatment from Drs. Shehzad Niazi and Jenny Smith, the physicians visited by the sales representatives identified in Plaintiffs' motion. *See* Reynolds Decl. Ex. 1 at 93-97, 363-64. Mr. Williams saw Dr. Niazi only once and continued to be treated by Dr. Smith, both of whom are psychiatrists who Mr. Williams saw for symptoms unrelated to the hip pain for which Dr. Browder prescribed Cymbalta.

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[1] *See Hagan-Brown v. Eli Lilly & Co.*, 1:14-cv-01614 (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly); *Ali v. Eli Lilly & Co.*, 1:14-cv-01615 (E.D. Va. Sept. 1, 2015) (same); *Herrera v. Eli Lilly & Co.*, No. 2:13-cv-02702 (C.D. Cal. Aug. 10, 2015) (defense verdict for Lilly on all claims); *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-02701 (C.D. Cal. Aug. 18, 2015) (directed verdict for Lilly); *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391 (S.D.N.Y. 2014) (judgment for Lilly on adequacy of warning); *Carnes v. Eli Lilly & Co.*, No. 0:13-591-CMC, 2013 WL 6622915 (D.S.C. Dec. 16, 2013) (granting summary judgment to Lilly).

II. The Discovery Record

A. Lilly's Extensive Production of Marketing and Promotional Materials

Lilly has already produced more than 35,000 pages of documents relating to Lilly's communication with physicians, including Mr. Williams' physicians. *See* Reynolds Decl. ¶ 3. Among these documents are sales representative training materials, sales call trackers, and advertising and promotional materials. These documents are only a subset of the extensive discovery record in this litigation. Over the past three years of litigation, Lilly has produced more than three million pages of documents, and there have been eleven depositions of current and former Lilly employees,[2] including 30(b)(6) depositions on a range of topics.[3] This discovery touches on all aspects of the life cycle of Cymbalta, including development, approval, marketing, and post-marketing surveillance.

B. The Discovery Dispute at Issue

Plaintiffs' motion follows a long negotiation between the parties on the scope of sales representative discovery, including in other related cases being handled by the same counsel.

1. Plaintiffs' Original Requests and the Parties' Discussions

In their First Requests for Production of Documents, Plaintiffs requested production of the complete "custodial file" — a term Plaintiffs do not define — of every Lilly sales representative who called on Mr. Williams' doctors regarding Cymbalta and every document that those representatives showed to or left with those doctors. *See* Def. Amended Objs. & Resp. to Pls. First Set of Requests for Production No. 91 at 62-63, Ex. 2. Lilly objected to this request as overbroad, unduly burdensome, and not limited to Cymbalta and discontinuation-emergent adverse events. *See id.* at 63-64.

Lilly did, however, produce to Plaintiffs a set of call tracking spreadsheets of the sales representatives who called on Mr. Williams' physicians, which list the sales representatives by name and

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[2] This total does not include Lilly sales representatives deposed in other Cymbalta lawsuits.

[3] Lilly's document productions in other, related Cymbalta discontinuation lawsuits have been produced to Plaintiffs here, and the depositions of Lilly witnesses were cross-noticed in this litigation and are also, by agreement, applicable here.

provide detail about the dates of their visits to Mr. Williams' physicians. Lilly also identified the sales representatives who called on Mr. Williams' physicians in its responses to Plaintiffs' interrogatories.

On September 23, 2015, Plaintiffs' counsel wrote to Lilly's counsel, listing nine of the sales representatives who had called on Mr. Williams' physicians, along with a date range for each of the representatives. *See* Reynolds Decl. Ex. 3. As detailed in the correspondence appended to this Memorandum, counsel for the parties agreed on a set of search terms for collecting and reviewing potentially-responsive documents for this and other Cymbalta cases where the parties are represented by the same counsel. *See* Reynolds Decl. Exs. 4-5. Plaintiffs also made additions and deletions to the list of sales representatives from whom they seek discovery, ending up with a list of six. *See* Reynolds Decl. Ex. 6 at 11-13.

Consistent with its position in other cases, Lilly agreed to provide search-term-limited email files of sales representatives who called on the physicians who prescribed Cymbalta to Mr. Williams or who supervised Mr. Williams' discontinuation from Cymbalta. *See id.* at 13. Here, no Lilly representatives visited Dr. Browder, who both prescribed Cymbalta to Mr. Williams and gave instructions for its discontinuation. As Lilly noted, the sales representatives from whom Plaintiffs sought discovery only called on physicians who treated Mr. Williams some five months after he discontinued Cymbalta, so their communications could not possibly have a bearing on the decision to prescribe Cymbalta. *See id.* at 10.

2. Plaintiffs' Counsel Seeks to Withdraw Agreement to Date Limitations

On March 8, 2016, Plaintiffs for the first time indicated that they no longer believed that date restrictions — which they had proposed in their September 23, 2015 letter — were appropriate. *See id.* at 2. Lilly had agreed to those date limitations, and similar date limits have been applied during the process of collecting and producing sales representative documents in other cases litigated by the same counsel. Plaintiffs also made a new proposal regarding whose custodial files they sought, offering to withdraw their request for the custodial files of the six sales representatives if Lilly would agree to provide custodial files of three Lilly district managers who supervised those representatives. *See id.* Lilly declined Plaintiffs' proposal on the same basis it had earlier articulated. *See id.* at 1.

LEGAL STANDARD

Under Rule 26, the scope of discovery is limited to nonprivileged, relevant materials that are "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1).[4] While the concept of proportionality has long formed part of Rule 26, s*ee Nicholas v. Wyndham Intern., Inc.*, 373 F.3d 537, 543 (4th Cir. 2004), it was recently highlighted by the 2015 amendments to the rule, which "restore[d] the proportionality factors to their original place in defining the scope of discovery" in subsection (b)(1) to "reinforce[] the Rule 26(g) obligation of the parties to consider these factors in making discovery requests . . ." Fed. R. Civ. P. 26(b)(1) Advisory Comm. Note (2015). *See Eramo v. Rolling Stone LLC*, --- F.R.D. ---, 2016 WL 304319, *2 n. 2 (W.D. Va. Jan. 25, 2016) ("[G]iven the 2015 amendment, the court will put a greater emphasis on the need to achieve proportionality, in determining whether to grant [a] motion to compel.").[5] Even indisputably relevant materials are not discoverable where the discovery sought lacks proportionality to the needs of the case. *See Henry v. Morgan's Hotel Group, Inc.*, No. 15-cv-789, 2016 WL 303114 at *3 (S.D.N.Y. Jan 25, 2016) ("[T]he amended Rule is intended to encourage judges to be more aggressive in identifying and discouraging discovery overuse by emphasizing the need to analyze proportionality before ordering production of relevant information.") (internal quotation marks and citation omitted).

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[4] Although relevancy is construed liberally, "[n]o one would suggest that discovery should be allowed of information that has no conceivable bearing on the case." *Republican Party of North Carolina v. Martin*, 136 F.R.D. 421, 425 (E.D.N.C. 1991) (quoting C. Wright & A. Miller, *Federal Practice and Procedure*) (internal quotation marks omitted).

[5] The purpose of the 2015 amendments was "to focus discovery . . . on what is truly necessary to resolve the case . . ." *Kissing Camels Surgery Ctr., LLC v. Centura Health Corp.*, No. 12-CV-03012-WJM-NYW, 2016 WL 277721, at *1 (D. Colo. Jan. 22, 2016) (citing Roberts, C.J., 2015 Year-End Report on the Federal Judiciary).

ARGUMENT

Plaintiffs' claims center on whether Lilly failed to warn Mr. Williams' prescribing physician about the risk of discontinuation. Lilly would have no objection to providing, subject to an agreement with Plaintiffs as to the scope of collection and appropriate search terms, materials from the files of selected sales representatives who called upon Mr. Williams' prescribing physician, Dr. Browder, or to allowing Plaintiffs to depose a reasonable number of those representatives. Indeed, in other cases where those materials are available, Lilly has provided them. But the fact that no Lilly sales representative called upon Dr. Browder regarding Cymbalta should not open up discovery concerning sales representatives who called upon physicians who did *not* prescribe Cymbalta to Mr. Williams. Those physicians' communications with Lilly about Cymbalta cannot possibly have had a bearing on whether Mr. Williams was prescribed Cymbalta or how he was eventually advised to discontinue the medicine. In addition to the lack of relevance, the burden of such additional discovery on top of the immense discovery already provided bears no reasonable proportion to the needs of this case.

I. The Discovery Sought By Plaintiffs Has Minimal Relevance

Plaintiffs insist that Lilly's sales representatives' communications with the physicians who saw Mr. Williams five months after he discontinued Cymbalta are "highly relevant" to their claims. Pl. Mem. at 5. But in support of their assertion, Plaintiffs point to examples highlighting the relevance of *prescribing* physicians. For instance, plaintiffs cite to an order from *Hexum v. Eli Lilly and Co.*, No. 2:13-cv-02701 (C.D. Cal.), another Cymbalta suit in which the Court granted Lilly's directed verdict motion. But the dispositive evidence in *Hexum* was the *prescribing physician's* knowledge of Cymbalta's risks and benefits and whether he had read the Cymbalta label, not the knowledge of physicians who did not treat the plaintiff until months after stopping Cymbalta.

Other cases cited by Plaintiffs similarly focus on discovery related to communications to prescribing physicians. *See In re Actos (Pioglitazone-Prods. Liab. Litig.)*, No. 6:11-MD-2299, 2013 WL 4776346, at *4-6 (W.D. La. Sept. 3, 2013) (granting discovery of sales representative files to establish whether information known to the defendant was communicated to plaintiff's prescribing physicians);

Cunningham v. Smithkline Beecham, 255 F.R.D. 474, 479 (N.D. Ind. 2009) (considering discovery of files of sales representatives who called the plaintiff's prescribing physician).[6] Plaintiffs do not cite a single case supporting their argument that physicians who simply record a plaintiff's symptoms have the same relevance as the doctor who made the decision to prescribe Cymbalta in the first instance.

Further, Plaintiffs cite no support for their assertion that "courts and juries deciding other Cymbalta withdrawal cases have focused on whether plaintiffs sought treatment for their withdrawal symptoms and whether plaintiffs were diagnosed with Cymbalta withdrawal." Pl. Mem. at 6. In fact, the two courts that granted summary judgment in Lilly's favor did so by looking to the testimony of the plaintiff's Cymbalta *prescriber*, not any other physician. *See McDowell*, 58 F. Supp. 3d at 406-07 (granting summary judgment to Lilly because of prescriber's knowledge of discontinuation risks); *Carnes*, 2013 WL 6622915 at *6-*7 (granting summary judgment to Lilly because of prescribers' knowledge of discontinuation risks). Moreover, Plaintiffs' prediction that "Lilly's anticipated defenses focus on the treating doctors' knowledge of Cymbalta and its risks," Pl. Mem. at 7, is undermined by the fact that Lilly does not even plan to depose Drs. Smith and Niazi.[7]

Any arguable relevance of the files of the sales representatives who called upon Drs. Niazi and Smith is further undermined by the fact that all but one of the sales representatives whose files Plaintiffs seek last called upon Drs. Niazi and Smith *years* before those physicians saw Mr. Williams. Mr. Williams first saw Drs. Niazi and Smith in August 2012, but as shown in the records that Lilly produced to Plaintiffs, Tracy Gaskins last called on Dr. Smith in December 2009; William Booth last called on Dr. Smith in March 2010; Kevin De Bruhl last called on Dr. Smith in May 2006; Gay Bolenbaugh last called

[6] A third case cited by Plaintiffs, *Baker v. Bayer Healthcare Pharm. Inc.*, No. 13-cv-00490, 2014 WL 5513854 (N.D. Cal. Oct. 31, 2014), concerned *call notes* showing sales representatives' visits to doctors, not custodial files. In this case, Lilly has already produced the available notes of the representatives that Plaintiffs requested, which show Lilly's sales representatives' visits to all of Mr. Williams' physicians.

[7] Although Lilly served deposition notices for Drs. Niazi and Smith because they were identified as relevant person with knowledge in Plaintiffs' Rule 26(f) disclosures, Lilly has withdrawn those notices after fully reviewing the medical records collected and no longer intends to depose those two physicians.

on Dr. Niazi in June 2008; and John Burke last called on Dr. Niazi in April 2009. To take just one example, it strains plausibility to suggest that any brief interaction that Kevin De Bruhl had with Dr. Smith *six to eight years* before Mr. Williams became Dr. Smith's patient could possibly have any bearing on Plaintiffs' claims, particularly where Dr. Smith did not prescribe Cymbalta to Mr. Williams.

II. Lilly Has Produced Extensive Information On Its Communications With Doctors

Lilly has produced a robust universe of materials on Cymbalta's marketing and promotion, much of it touching on information Lilly communicated to doctors, including:

- Advertisements and promotional materials: over 15,000 documents comprising advertisements and promotional materials directed either at healthcare professionals or consumers.
- Spreadsheets showing visits by Lilly sales representatives and third-party contractors to Plaintiff's physicians.
- Annual brand strategy documents developed by the Cymbalta brand team.

Although Lilly does not concede the ultimate admissibility of these documents at trial, they go directly to the issues of ostensible concern to Plaintiffs — Lilly's communication with doctors, including Mr. Williams' doctors. Because Plaintiffs have such information, and are free to depose Mr. Williams' physicians to inquire how their interactions with Lilly representatives or any materials they received impacted their treatment decisions, it is difficult to see how additional discovery from the representatives who called on Drs. Niazi and Smith could add to the discovery bearing on the central issues in this case.

III. Plaintiffs' Discovery Proposal Violates Principles of Proportionality

Even if the Court finds that the documents compelled here are relevant — and Lilly maintains that they are not — in order for these materials to fall within the scope of discovery, the Court must also find that they are "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Olivares v. University of Chicago*, No. 1:15-cv-713, 2016 WL 126757 (M.D.N.C. Jan. 11, 2016) (quoting Fed. R. Civ. P. 26(b)(1)). "[W]hen discovery

requests approach the outer bounds of relevance and the information sought may only marginally enhance the objectives of providing information to the parties or narrowing the issues, the court must then weigh the request with the hardship to the party from whom the discovery is sought." *Piazza's Seafood World, L.L.C. v. Odom*, No. 07–413–BAJ–CN, 2011 WL 3664437, at *2 (M.D. La. Aug. 19, 2011).

The possible discovery of the sales representative files at issue here does not meet the Federal Rules' requirements for proportionality, because to produce them places a burden on Lilly not justified by their marginal relevance. Collecting these files will require Lilly to run searches across both Lilly's current and archived email systems for a particular sales representative's name in the to/from/cc/bcc fields, then applying the agreed-upon search terms across those isolated collections. The results must then be de-duplicated and reviewed by attorneys for privilege and relevance. Plaintiffs' argument that Lilly could alleviate this burden by foregoing a relevance review, *see* Pl. Mem. at 8, asks Lilly to abandon the contours of discovery under Rule 26. Lilly should not be penalized for insisting on procedures that limit its production to only relevant documents in the scope of discovery. *See Makowski vs. SmithAmundsen LLC*, No. 08 C 6912, 2012 WL 1634832, at *3 (N.D. Ill. May 9, 2012) ("The Court will not waste time assessing . . . the applicability of a claim of privilege as to irrelevant documents that happen to contain a search term but have nothing to do with the issues in this lawsuit. . . .").[8] Indeed, the court in another Cymbalta discontinuation lawsuit has rejected plaintiffs' argument that Lilly should forego relevance review in favor of only using search terms. *See Wheeler v. Eli Lilly and Co.*, No. 14-cv-1882, ECF No. 63 at 18-19 (S.D. Cal. Jan. 19, 2016) ("Even when a search protocol has been agreed upon, it is not uncommon or inappropriate for a party to conduct a relevancy review of the documents found using the search protocol prior to producing any documents.").

[8] Plaintiffs also contend that Lilly has not provided sufficient "data" about the specific sales representative files at issue in this case to allow Plaintiffs to assess a claim of burden. But to do so would itself require searches of Lilly's current and archived email systems, the export, processing, and loading of any documents onto a review platform, and the application of search terms to provide a "hit report." *See* Reynolds Decl. ¶ 4. Those efforts themselves are a substantial undertaking unjustified by the marginal relevance of the documents at issue here.

While Lilly recognizes this is not an overwhelming burden, it nevertheless outweighs the likely benefit of such peripheral discovery. Given the marginal importance of the proposed discovery, the proportionality principles of Rule 26 dictate that such discovery is unjustified.

IV. Date Ranges Are Appropriate for Narrowing Discovery

As articulated above, Lilly's position is that any discovery of the files of sales representatives who called on Drs. Niazi and Smith is not relevant and violates the principles of proportionality. However, should the Court determine that some discovery of sales representatives' files is appropriate, the Court should also order that Plaintiffs must honor the parties' agreement that a date restriction be used to narrow the discovery sought and minimize Lilly's burden in reviewing and producing documents.

Plaintiffs themselves first proposed the use of a date restriction when they first identified specific sales representatives whose files they sought. *See* Reynolds Decl. Ex. 3. Although Lilly objects to the proposed sales representative discovery in this case on other grounds, Lilly has never objected to the use of date range restrictions to narrow the scope of discovery. Plaintiffs' proposed date restrictions make sense: they reflect the outer bounds of the period during which each sales representative regularly called upon the relevant physician. Indeed, date restrictions have been applied in the context of sales representative discovery in other Cymbalta cases being handled by the same counsel representing the parties in this matter. And date ranges are commonly used to narrow the scope of discovery. *See, e.g.,* Thomas Y. Allman, Conducting E-Discovery After the Amendments: The Second Wave, 10 Sedona Conf. J. 215, 217 (2009) ("Courts expect parties to reach practical agreement on . . . date ranges . . . ."). In the event that Plaintiffs' original proposed date ranges are applied in this case, the only materials excluded will be documents dating from before or after the sales representative's interactions with Mr. Williams' physicians. At best, such documents are of exceedingly marginal relevance, because they cannot possibly contain any information about "what Lilly's representatives communicated to Dr. Niazi and Dr. Smith," which is Plaintiffs' own explanation for why the sales representative files are relevant. Pl. Mem. at 6.

CONCLUSION

For the foregoing reasons, Lilly respectfully asks the Court to deny Plaintiffs' motion to compel production of the six sales representative files in its entirety.

Dated: April 4, 2016

Respectfully Submitted,
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CERTIFICATE OF SERVICE

I, Paul J. Osowski, hereby certify that on the 4th day of April, 2016, I have served Plaintiffs' counsel in this action with a copy of Defendant's Opposition to Plaintiffs' Motion to Compel by filing the same through the Court's ECF system, which will effect service on:

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